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Magali Rouquie

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EXAMINER

SKOWRONEK, KARLHEINZ R

ART UNIT

PAPER NUMBER

1631

NOTIFICATION DATE

DELIVERY MODE

01/22/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/568,718	Applicant(s) ROUQUIE ET AL.	
	Examiner KARLHEINZ R. SKOWRONEK	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-12 is/are rejected.
- 7) ☒ Claim(s) 2-5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Status

Claims 2-12 are pending.

Claim 1 is cancelled.

Claim 12 is new.

Claims 2-12 have been examined.

Claims 2-12 are rejected.

Claims 2-5 are objected to.

Priority

This application is the National Stage filing under 35 USC 371 of PCT/FR2004/02115, filed on 10 August 2004, and claims priority to earlier application No. 0309983 file in France on 18 August 2003.

Specification

The objection to the abstract is withdrawn in view of the amendment the abstract.

Claim Objections

The objection to claims 4-11 is withdrawn in view of the amendments to the claims.

The objection to claim 3 is withdrawn in view of the amendments to the claims.

The following objection is necessitated by amendment of the claims.

Claims 2-5 are objected to because of the following informalities:

Claim 5 contains the typographical error in which the term "translational" is misspelled as "traductional" in line 4 of claim 5.

In claim 5, the precision of the claim with respect to the recited “covalent transformation itself” and “non-covalent transformation itself” could be improved by removing the term “itself” from lines 3 and 7.

In claims 2- 5, the claim recites nested Markush-like alternatives at line 2 of claim 2; at line 2 of claim 3; at line 2 of claim 4; at lines 2, 3, 6, and 7 of claim 5. The claim clarity would be improved by amending “selected from” at lines 2, 3, 6, and 7 of claim 5 to recite, "selected from the group consisting of".

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 2-12 are directed to a process of modeling and simulating a biological system. The following analysis is taken from the guidance provided in the MPEP at 2104.IV, “Determine Whether the Claimed Invention Complies with 35 USC101”. The claims are directed to processes. Here the claims are directed to the abstract idea of representing the functions of a cell as simulated in a model. The processes do not recite a physical transformation of matter from one state to another. Giving the claims the broadest reasonable interpretation, the claims read on mental steps. In *Comiskey (In re Comiskey*, 84 USPQ2d 1670) the court established that “the application of human intelligence to the solution of practical problems is not

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and of itself patentable” (at 1680). In *Comiskey*, the court stated explicitly “mental processes - or processes of human thinking - standing alone are not patentable even if they have a practical application” (at 1679). The court in *Comiskey* stated, “Following the lead of the Supreme Court, this court and our predecessor court have refused to find processes patentable when they merely claimed a mental process standing alone and untied to another category of statutory subject matter even when a practical application was claimed” (at 1680). The court’s recent decision in *In re Bilski* confirmed, “a process is patent-eligible under 35 USC 101 if it is tied to a particular machine or apparatus or if it transforms a particular article into a different state or thing” (*In re Bilski*, 88 USPQ at 1391, 2008). In the instant claims, the process is not tied to a class of statutory invention. Output is insignificant post-solution activity and does not represent a significant tie to another category of invention. The court in *Comiskey*, stated “the court rejected the notion that mere recitation of a practical application of an abstract idea makes it patentable, concluding that ‘[a] competent draftsman could attach some form of post-solution activity to almost any mathematical formula’” citing *Flook* (437 U.S. at 586, 590). The recent decision in *Bilski* confirmed the court’s position regarding insignificant pre- or post-solution activity (i.e. insignificant extra-solution activity) as stated in *Comiskey* (see *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008) at p. 1396-1397). Applicant is encouraged to consider the recent BPAI informative decisions *Exparte Langemyr* (No. 2008-1495 (28 May 2008)) and *Exparte Biliski* (No. 2002-2257 (26 September 2006)) for further clarification of the above grounds of rejection.

Response to Arguments

Applicant's arguments filed 29 October 2009 have been fully considered but they are not persuasive. Applicant argues the claims recite statutory subject matter because that data representing the tangible biological entity are modified thereby simulating a transformation of the entities from one state to another. The argument is not persuasive. The modification of the data to simulate a transformation is not a transformation of the data from one state to another. After the modification, the data remain data. The claimed invention is not tied to a particular machine nor does the claimed invention transform the underlying subject matter to a different state or thing. The rejection is maintained.

Claim Rejections - 35 USC § 112

Response to Arguments

The rejection of claim 1 under 35 USC 112, second paragraph as indefinite is withdrawn in view of the cancellation of claim 1.

The rejection of claim 3 under 35 USC 112, second paragraph is withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2- 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Thalhammer-Reyero (US PAT 5,930,154).

The claims are directed to a method of modeling and simulating a biological system in which the effects on the function and behavior of the entity relative to changes in morphological, spatial, and temporal occurrences in the biological entity is determined. For the purpose of examination, the term “tangible biological functional entity” is broadly construed to mean any measurable object that has an effect relating to biology.

Thalhammer-Reyero shows a computer based system and method for the simulation and modeling of complex biological systems that are organized into discrete compartments in time and space. Thalhammer-Reyero shows that changes in morphological, spatial, and temporal occurrences affect the function and behavior of the entity (col. 17, line 32-61). Thalhammer-Reyero shows changes are determined recursively (col. 35, line 66 to col. 36, line 8). Thalhammer-Reyero shows morphological occurrences that comprise biochemical constituents and transformations representing spatio-temporal constituent behavior (col. 16, line 14-18). Thalhammer-Reyero shows spatial occurrences which are a representation of spatial characteristics of the biological entity (figure 12 and col. 4, line 54-60). Thalhammer-Reyero shows temporal occurrences that are characteristics of the biological entity specifically a period in which the biological entity is active (col. 14, line 47-50). With respect to claim 4, Thalhammer-Reyero shows that a transformation is a cellular transformation and a molecular transformation (col. 31, line 15-20). With respect to claim 5, Thalhammer-Reyero shows the molecular transformation is covalent (col. 31, line 18-29). With respect to claim 6, Thalhammer-Reyero shows that the some function biological entities

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are included in a higher biological functional entity (col. 15, line 59-64). With respect to claim 7, Thalhammer-Reyero shows that the some function biological entities are include in a lower biological functional entities (col. 15, line 59-64). With respect to claim 8, Thalhammer-Reyero shows that the some function biological entities constitute the environment of other biological functional entities with which they interact (figure 1). With respect to claim 9, Thalhammer-Reyero shows bioprocesses are intangible biological entities that are modeled by temporal occurrences and where applicable spatial and temporal occurrences (col. 27, line 5-20). With respect to claim 10, Thalhammer-Reyero shows intangible biological entities or bioprocesses comprise biochemical reactions or pathways. With respect to claim 11, Thalhammer-Reyero shows a model for implementing a method of simulating a biological system (figure 1).

Response to Arguments

Applicant's arguments filed 29 October 2009 have been fully considered but they are not persuasive. Applicant argues that Thalhammer-Reyero fails to show a frame of reference that consists of shape, time, and space. The argument is not persuasive. As exemplified in the specification a change in shape or morphology can be a change in the functional state of a molecule and can result when biological functional entities interact (specification p. 6, line 25-p. 7, line 3). The showing in Thalhammer-Reyero at col. 4, lines 54-56 indicated by applicant's arguments is in complete agreement with the reference frame of shape, time, and space. Applicant argues that Thalhammer-Reyero at col. 16, line 14-18 is irrelevant to changes in time and space because it only discusses populations of cells and molecules and their location. The argument is not

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persuasive. Thalhammer-Reyero at col. 16, line 14-18 states, "It is a characteristic of this invention the use of different bioPools to represent populations of a given type of cell or molecule in different states or conformations, and for each location of such populations in particular". The statement of Thalhammer-Reyero is directly related to a reference frame, as is instantly claimed, in which shape, morphology or conformation are combined with space or location and time, either short term or long term. Further supporting the teaching a shape, time, and space reference frame, Thalhammer-Reyero shows the wide range of knowledge forma involved in the dynamic simulation of biological mechanisms need a variety of techniques to simultaneously represent knowledge about a) the high complexity of cells and organisms, and their activation and differentiation; b) the quantities of each entity in each state in each particular physiological or cellular compartment; c) the succession of states of an entity and their quantities over time; and d) the highly regulated interactions between specific states of those entities and the result forward and feedback loops and crass-talk between pathways (col. 10, line 51-61). Thus, Thalhammer-Reyero demonstrates a frame of reference that consists of time, shape, and space.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARLHEINZ R. SKOWRONEK whose telephone number is (571)272-9047. The examiner can normally be reached on 8:00am-5:00pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KARLHEINZ R SKOWRONEK/
Examiner, Art Unit 1631

20 January 2010